



6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[Docket ID No. EPA-HQ-ORD-2014-0859; FRL-10004-64-ORD]

Integrated Science Assessment for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of a final document titled, “Integrated Science Assessment for Particulate Matter” (EPA/600/R-19/188). The document was prepared by the Center for Public Health and Environmental Assessment (CPHEA) within EPA’s Office of Research and Development (ORD) as part of the review of the primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards (NAAQS) for particulate matter (PM) and represents an update of the 2009 Integrated Science Assessment (ISA) for PM. The welfare-based effects evaluated consist of non-ecological effects, specifically visibility impairment, climate effects, and effects on materials. The ISA provides the scientific basis for EPA’s decisions, in conjunction with additional technical and policy assessments, on the adequacy of the current NAAQS and the appropriateness of possible alternative standards. EPA is currently developing a separate ISA to support the secondary NAAQS review for ecological effects for oxides of nitrogen, oxides of sulfur, and particulate matter.

DATES: The document is available on or about January 6, 2020.

ADDRESSES: The “Integrated Science Assessment for Particulate Matter (Final)” will be available primarily via the internet on EPA’s Integrated Science Assessment Particulate Matter

page at <https://www.epa.gov/isa/integrated-science-assessment-isa-particulate-matter> or the public docket at <http://www.regulations.gov>, Docket ID: **EPA-HQ-ORD-2014-0859**. A limited number of CD-ROM copies will be available. Contact Ms. Marieka Boyd by phone: 919-541-0031; fax: 919-541-5078; or email: boyd.marieka@epa.gov to request a CD-ROM, and please provide your name, your mailing address, and the document title, “Integrated Science Assessment for Particulate Matter” to facilitate processing of your request.

FOR FURTHER INFORMATION, CONTACT: For technical information, contact Mr. Jason Sacks, CPHEA; phone: 919-541-9729; fax: 919-541-1818; or email: sacks.jason@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Information About the Document

Section 108(a) of the Clean Air Act directs the Administrator to identify certain pollutants which, among other things, “cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare” and to issue air quality criteria for them. These air quality criteria are to “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air...” Under section 109 of the Act, EPA is then to establish NAAQS for each pollutant for which EPA has issued criteria. Section 109(d) of the Act subsequently requires review every five years and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health or welfare. EPA is also required to review and, if appropriate, revise the NAAQS, based on the revised air quality criteria (for more information on the NAAQS review process, see <http://www.epa.gov/ttn/naaqs/review.html>).

Particulate matter is one of six criteria pollutants for which EPA has established NAAQS. Periodically, EPA reviews the scientific basis for these standards by preparing an ISA (formerly called an Air Quality Criteria Document). The ISA provides the scientific basis for EPA's decisions, in conjunction with additional technical and policy assessments, on the adequacy of the current NAAQS and the appropriateness of possible alternative standards. The Clean Air Scientific Advisory Committee (CASAC), an independent science advisory committee whose review and advisory functions are mandated by Section 109(d)(2) of the Clean Air Act, is charged (among other things) with independent scientific review of the EPA's air quality criteria.

On December 3, 2014 (79 FR 71764), EPA formally initiated its current review of the air quality criteria for the health and welfare effects of particulate matter and the primary (health-based) and secondary (welfare-based) NAAQS, requesting the submission of recent scientific information on specified topics. EPA conducted a workshop from February 9 to 11, 2015 to gather input from invited scientific experts, both internal and external to EPA, as well as from the public, regarding key science and policy issues relevant to the review of the primary and secondary NAAQS (79 FR 71764). These science and policy issues were incorporated into EPA's "Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter," which was available for public comment (81 FR 22977) and discussion by the CASAC via publicly accessible teleconference consultation (81 FR 13362). The "Final Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter" was released December 6, 2016 (81 FR 87933).

Subsequent webinar workshops were held on June 9, 13, 20, and 22, 2016, to discuss initial draft materials prepared in the development of the particulate matter ISA with invited EPA

and external scientific experts (81 FR 29262). The input received during these webinar workshops aided in the development of the materials presented in the “Integrated Science Assessment for Particulate Matter (External Review Draft), which was released on October 23, 2018” (83 FR 53471), and is available at:

<https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=341593>. The CASAC met at a public meeting on December 12 – 13, 2018 (83 FR 55529), to review the draft PM ISA. A public teleconference was then held on March 28, 2019 for CASAC to review their draft letter to the Administrator on the draft ISA. This meeting was announced in the *Federal Register* on March 8, 2019 (84 FR 8523). Subsequently, on April 11, 2019, the CASAC provided a letter of their review to the Administrator of the EPA, available at:

[https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002+.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002+.pdf). The letter from the CASAC, as well as public comments received on the draft PM ISA, can be found in Docket ID No. EPA-HQ-ORD-2014-0859.

The Administrator responded to the CASAC’s letter on the External Review Draft of the PM ISA on July 25, 2019, and is available at:

[https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002_Response.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002_Response.pdf). Administrator Wheeler’s letter to the CASAC indicated the Agency will “incorporate the CASAC’s comments and recommendations, to the extent possible, and create a final PM ISA so that it may be available to inform a proposed decision on any necessary revisions of the NAAQS in early 2020.” The U.S.

EPA focused on addressing comments presented in the main body of the CASAC letter (i.e., the cover letter and consensus responses to charge questions), and to the extent possible, in the statutorily provided timeframe, addressed individual CASAC member comments as well as public comments on the draft PM ISA. The consensus CASAC comments on the draft PM Policy Assessment (December 16, 2019) stated “...the Draft PM ISA, does not provide a comprehensive, systematic review of relevant scientific literature; inadequate evidence and rationale for altered causal determinations; and a need for clearer discussion of causality and causal biological mechanisms and pathways.” To address these comments in the Final PM ISA, the EPA: (1) added text to the Preface and developed a new Appendix to more clearly articulate the process of ISA development; (2) revised the causality determination for long-term ultrafine particle (UFP) exposure and nervous system effects to *suggestive of, but not sufficient to infer, a causal relationship*; and (3) added additional text to the Preface of the PM ISA as well as text in the health effects chapters to clarify the discussion of biological plausibility and its role in forming causality determinations. Additionally, the U.S. EPA focused on addressing those comments that contributed to improving clarity, could be addressed in the near-term, and identified errors in the draft PM ISA. Lastly, Administrator Wheeler noted, “for those comments and recommendations that are more significant or cross-cutting and which were not fully addressed, the Agency will develop a plan to incorporate these changes into future PM ISAs as well as ISAs for other criteria pollutant reviews.”

Dated: December 31, 2019.

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and Environmental Assessment.

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